

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 18, 2009 has been entered.

**Detailed Action**

This office action is a response to applicant's information disclosure statement submitted September 18, 2009. This application is a national stage application of PCT/GB04/03488, filed August 12, 2004, which claims priority to foreign applications EP03254988.3, filed August 12, 2003, and EP03255200.2, filed August 12, 2003.

Claims 1, 4-10, 21-24, 30, and 31 are pending in this application and examined on the merits herein.

**Reasons for Allowance**

Applicant's information disclosure statement submitted September 18, 2009 has been fully considered and not found to be the basis for any new grounds of rejection against the claims previously allowed in the office action of June 18, 2009. Although many of the references cited in the information disclosure statement, for example Jain

et al., Gregoriadis et al., or WO01/87922, disclose conjugation of polysialic acid with proteins, all of these references disclose a conjugation method in which the acyclic polyol group at the non-reducing end of the polysialic acid is oxidized to form an aldehyde which can be reacted with nucleophiles. By contrast, the compounds included in the claims require that the pendant moiety be attached at the reducing end of the polysaccharide. As discussed in the notice of allowance submitted June 18, 2009, the prior art methods are specific for introduction of the pendant moiety at the non-reducing end and modifying them to introduce the moiety at the reducing end would introduce additional complexity and difficulty into the process of making the compound for no expected benefit, since the prior art gives no reason to believe that the reducing end conjugate would possess any advantages against the disclosed non-reducing end conjugate.

Although Macmillan et al. does disclose glycosylation methods in which a glucosamine sugar is attached to erythropoietin using a pendant linker moiety at the anomeric position, one of ordinary skill in the art would not have made the leap from this method to attaching a similar linker to the anomeric position of the reducing sugar of polysialic acid. Firstly, polysialic acid possesses an easily modified triol group at the nonreducing end, which allows for easy incorporation at this non-reducing position by oxidation and Schiff base formation. Secondly, the anomeric position of polysialic acid is sterically hindered and not as readily available for conjugation as the less hindered anomeric position of glucosamine. Therefore, one of ordinary skill in the art would not

have seen any benefit to using this conjugation technique to attach polysialic acid to a protein over the known non-reducing end conjugation.

For these reasons the submitted references do not form the basis for any new grounds of rejection against the previously allowed claims. The claims are therefore found allowable for the reasons disclosed in the office action of June 18, 2009 and as discussed above.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Examiner, Art Unit 1623  
11/5/2009

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623